



SEALED

Office of the United States Attorney
District of Nevada
501 Las Vegas Boulevard, Suite 1100
Las Vegas, Nevada 89101
(702) 388-6336

1 DAYLE ELIESON
United States Attorney
2 District of Nevada
ROBERT A. KNIEF
KILBY MACFADDEN
3 Assistant United States Attorneys
501 Las Vegas Boulevard South, Suite 1100
4 Las Vegas, Nevada 89101
Phone: 702-388-6336
5 Fax: 702-388-6418
robert.knief@usdoj.gov
6 kilby.macfadden@usdoj.gov
Representing the United States of America

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8 UNITED STATES DISTRICT COURT
9 DISTRICT OF NEVADA

10 -oOo-

11 UNITED STATES OF AMERICA,

12 Plaintiff,

13 vs.

14 STEVEN A. HOLPER, M.D.,

15 Defendant.

SEALED
CRIMINAL INDICTMENT

Case No.: 2:18-CR - 37

Violations:

21 U.S.C. § 841(a)(1) & (b)(1)(C) –
Distribution of a Controlled Substance
(Schedule II)

18 U.S.C. §1035(a)(2) – False Statement
Relating to a Health Benefit Program

20 THE GRAND JURY CHARGES THAT:

21 At times material to this Indictment:

22 Introduction

23 1. The Defendant, Steven A. Holper M.D. ("Holper") is a licensed physician who
24 has practiced medicine in Nevada since 1990 under Nevada License Number

1 6061. He maintains his medical practice at 3233 West Charleston Blvd # 202, Las
2 Vegas, Nevada.

3 2. Defendant Holper's practice area is pain management. As part of his practice,
4 he prescribes Controlled Substances, including opioids, with a Drug Enforcement
5 Administration ("DEA") license number BH2498106.

6 3. Under the Controlled Substances Act, Title 21, United States Code, Section
7 841(a) *et seq.*, and Title 21, Code of Federal Regulations, Section 1306.04, a
8 prescription for a controlled substance is not legal or effective unless it was issued
9 for a legitimate medical purpose by a practitioner acting in the usual course of
10 professional practice.

11 4. Fentanyl, a Schedule II controlled substance, is a powerful synthetic opioid
12 painkiller that is 100 times more potent than morphine and 40 to 60 times more
13 potent than 100% pure heroin. When legally prescribed for a legitimate medical
14 purpose, fentanyl typically is used for the management of breakthrough cancer
15 pain in cancer patients who are already receiving opioid medication for their
16 underlying persistent pain. Fentanyl is available in various forms, including
17 Subsys, which is a sublingual spray of fentanyl manufactured by INSYS
18 Therapeutics. Subsys is a Schedule II Controlled Substance.

19 5. Subsys is only available through the Transmucosal Immediate-Release
20 Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access
21 program.
22

23 6. TIRF drugs are a subset of potent fentanyl-based drugs. TIRF drugs are sold
24 under several brand names, including Subsys.

1 7. Because of the extreme risk of misuse, abuse, addiction, and overdose death
2 associated with TIRF drugs, the FDA requires that all practitioners,
3 pharmacists, and patients must be enrolled in an FDA REMS program before
4 they are allowed to prescribe, dispense, or take Subsys.

5 8. The only FDA-approved indication for TIRF drugs is "for the management of
6 breakthrough pain in patients with cancer who are already receiving, and who
7 are tolerant to, around-the-clock opioid therapy for their persistent pain." There
8 are no off-label uses approved for TIRF drugs, like Subsys.

9 9. Before prescribing a TIRF drug to a patient, the prescriber must fill out and
10 sign a REMS form that explicitly states, "I understand that TIRF medicines are
11 indicated only for the management of breakthrough pain in patients with cancer
12 who are already receiving, and who are tolerant to, around-the-clock opioid
13 therapy for their underlying persistent pain."

14 10. Patients and their caregivers must be instructed that TIRF medicines contain
15 medicine which in any amount can be fatal to children, individuals for whom it
16 is not prescribed, and to those who are not opioid-tolerant. Patients and
17 caregivers must be advised to dispose of used unit dose systems immediately after
18 use, and any unneeded unit dose systems remaining from a prescription, as soon
19 as they are no longer needed.
20

21 11. Defendant Holper is both a recipient and prescriber of Subsys. As a medical
22 professional and patient, he is aware of the legitimate medical purpose for
23 prescriptions of Subsys, as well as the prescription regulations of TIRF REMS
24

1 and the dangers of fentanyl, especially to those who are not opioid tolerant or
2 under the age of 18, based on his required TIRF REMS Access Program training.

3 12. On or about approximately January 27, 2015, Defendant Holper, approved
4 Patient A's enrollment in the TIRF REMS Access Program, fraudulently stating
5 that Patient A had been prescribed other Schedule II prescriptions, without
6 success. Patient A had employer-provided health insurance.

7 13. Holper prescribed Subsys to Patient A, who did not have cancer, in violation
8 of the TIRF REMS Access Program guidelines. From on or about September 2014
9 to March 2016, Defendant Holper prescribed outside the usual course of
10 professional practice and without a legitimate medical purpose, and then illegally
11 distributed fentanyl in the form of Subsys to Patient A.

12 14. Defendant Holper also prescribed various Schedule II controlled substances
13 including Subsys, Hydromorphone, and OxyContin for Patient A from
14 approximately April 18, 2013 until June 2015. He last prescribed Subsys 600 mcg
15 spray 60 on or about June 8, 2015 to Patient A.

16 15. From on or about July 2015 through in or about March 2016, after Defendant
17 Holper stopped prescribing Subsys to Patient A, he regularly provided Patient A
18 Subsys canister sprays, without a prescription.

19 16. Patient A used a small tool to open the Subsys canister sprays to access the
20 remaining fentanyl. Patient A then used a syringe to inject the fentanyl into
21 his/her arm.

22 17. On Saturday, March 12, 2016, Patient A retrieved used Subsys canisters from
23 Defendant Holper's residence in the late morning. Later the day, Patient A died.
24

1 His/her death was ruled accidental and a condition relating to his/her cause of
2 death was classified as Fentanyl intoxication.

3 18. In fatalities from fentanyl, blood concentrations are variable and have been
4 reported as low as 3 ng/mL. Patient A's fentanyl level was approximately 12
5 ng/mL when he/she died. Hundreds of Subsys canister sprays were found in and
6 around Patient A's bedroom, bathroom, work place, and vehicle after Patient A's
7 death. If Patient A had not used remaining fentanyl from the used Subsys
8 canisters Patient A received from Defendant Holper, Patient A would not have
9 died when he/she did.

10 19. As part of his medical practice, Defendant Holper prescribed Subsys to his
11 patients, Patients A-V, who did not have cancer in violation of TIRF REMS
12 regulations, which resulted in health insurance providers continuing to pay for
13 Subsys prescriptions.
14

15 **COUNTS ONE THROUGH SEVEN**
16 *(Distribution of Controlled Substances - Schedule II)*

17 The Grand Jury incorporates Paragraphs One through Nineteen as though
18 fully set forth herein.

19 On or about the dates set forth below, in the State and Federal District of
20 Nevada,

21 **STEVEN A. HOLPER,**

22 Defendant herein, did knowingly and intentionally distribute a mixture and
23 substance containing a detectable amount of a Schedule II controlled substance,
24

Fentanyl, as listed below, without a legitimate medical purpose and outside the usual course of professional practice, each of which constitutes a separate count of this Indictment:

Count	Approx. Date of Distribution	Patient	Controlled Substance
1	July 19, 2015	Patient A	Fentanyl, a/k/a "Subsys"
2	September 12, 2015	Patient A	Fentanyl, a/k/a "Subsys"
3	September 23, 2015	Patient A	Fentanyl, a/k/a "Subsys"
4	October 10, 2015	Patient A	Fentanyl, a/k/a "Subsys"
5	February 9, 2016	Patient A	Fentanyl, a/k/a "Subsys"
6	February 20, 2016	Patient A	Fentanyl, a/k/a "Subsys"
7	March 12, 2016	Patient A	Fentanyl, a/k/a "Subsys"

All in violation of Title 21, United States Code, Sections 841(a)(1) and (b)(1)(C); and Title 21, Code of Federal Regulations, Section 1306.04.

COUNTS EIGHT THROUGH TWENTY NINE

(False Statement Relating to a Health Benefit Program)

The Grand Jury incorporates Paragraphs One through Nineteen as though fully set forth herein.

On or about November 21, 2013, through March 24, 2017, in the State and Federal District of Nevada, and elsewhere,

STEVEN A. HOLPER,

Defendant herein, in a matter involving a health care benefit program, to wit: Medicare and Private Health Insurance, knowingly and willfully made a materially false, fictitious, and fraudulent statement, to wit: representing that Patients A-V all were cancer patients with breakthrough cancer pain, who were opioid tolerant and eligible for Subsys prescriptions, in connection with the delivery of and payment for health care benefits, items, and services, with each Patient, identified herein as Patients A-V, constituting a separate violation of Title 18, United States Code, Section 1035(a)(2).

<u>COUNT</u>	<u>Patient</u>	<u>Approx. Start Date</u>	<u>Approx. End Date</u>	<u>Unauthorized Prescription</u>	<u>Health Care Benefit</u>
8	Patient A	9.25.14	6.8.15	Subsys	Private Insurance Plan
9	Patient B	7.21.14	11.23.15	Subsys	Medicare
10	Patient C	10.22.14	10.15.15	Subsys	Medicare
11	Patient D	3.13.14	12.8.15	Subsys	Medicare
12	Patient E	11.21.13	1.2.15	Subsys	Medicare
13	Patient F	5.1.14	11.17.15	Subsys	Medicare
14	Patient G	3.27.2014	3.27.2014	Subsys	Medicare
15	Patient H	11.25.13	12.8.16	Subsys	Medicare
16	Patient I	7.23.15	11.20.15	Subsys	Private Insurance Plan
17	Patient J	8.5.14	11.24.15	Subsys	Medicare
18	Patient K	1.15.14	12.3.15	Subsys	Medicare
19	Patient L	1.13.14	12.4.15	Subsys	Medicare

<u>COUNT</u>	<u>Patient</u>	<u>Approx. Start Date</u>	<u>Approx. End Date</u>	<u>Unauthorized Prescription</u>	<u>Health Care Benefit</u>
20	Patient M	1.3.14	12.4.15	Subsys	Medicare
21	Patient N	2.28.15	7.14.15	Subsys	Medicare
22	Patient O	6.18.14	11.20.15	Subsys	Medicare
23	Patient P	8.26.15	12.2.15	Subsys	Medicare
24	Patient Q	7.30.15	12.7.16	Subsys	Medicare
25	Patient R	7.29.15	3.13.17	Subsys	Medicare
26	Patient S	8.28.14	12.16.15	Subsys	Medicare
27	Patient T	3.24.15	12.8.15	Subsys	Medicare
28	Patient U	6.16.15	2.21.17	Subsys	Medicare
29	Patient V	1.9.15	11.31.16	Subsys	Medicare

FORFEITURE ALLEGATION ONE

(Distribution of Controlled Substances - Schedule II)

1. The allegations of Counts One through Seven of this Criminal Indictment are hereby realleged and incorporated herein by reference for the purpose of alleging forfeiture pursuant to Title 18, United States Code, Section 981(a)(1)(C) with Title 28, United States Code, Section 2461(c); Title 21, United States Code, Section 853(a)(1); Title 21, United States Code, Section 853(a)(2); and Title 21, United States Code, Section 881(a)(6) with Title 28, United States Code, Section 2461(c).

1 2. Upon conviction of any of the felony offenses charged in Counts One
2 through Seven of this Criminal Indictment,

3 **STEVEN A. HOLPER,**

4 Defendant herein, shall forfeit to the United States of America, any property,
5 real or personal, which constitutes or is derived from proceeds traceable to
6 violations of Title 21, United States Code, Section 841(a)(1), a specified unlawful
7 activity as defined in Title 18, United States Code, Sections 1956(c)(7)(A) and
8 1961(1)(D), or a conspiracy to commit such offense:

9 Defendant herein, shall forfeit to the United States of America, any property
10 constituting, or derived from, any proceeds obtained, directly or indirectly, as the
11 result of violations of Title 21, United States Code, Section 841(a)(1):

12 Defendant herein, shall forfeit to the United States of America, any property
13 used, or intended to be used, in any manner or part, to commit, or to facilitate the
14 commission of Title 21, United States Code, Section 841(a)(1):

15 Defendant herein, shall forfeit to the United States of America, all moneys,
16 negotiable instruments, securities, or other things of value furnished or intended to
17 be furnished in exchange for a controlled substance or listed chemical in violations
18 of Title 21, United States Code, Section 841(a)(1), all proceeds traceable to such an
19 exchange, and all moneys, negotiable instruments, and securities used or intended
20 to be used to facilitate any violation of Title 21, United States Code, Section
21 841(a)(1):

22 An in personam criminal forfeiture money judgment including, but not
23 limited to, at least \$3,504,912.21 (property).
24

1 3. If any property being subject to forfeiture pursuant to Title 18, United
2 States Code, Section 981(a)(1)(C) with Title 28, United States Code, Section 2461(c);
3 Title 21, United States Code, Section 853(a)(1); Title 21, United States Code,
4 Section 853(a)(2); and Title 21, United States Code, Section 881(a)(6) with Title 28,
5 United States Code, Section 2461(c), as a result of any act or omission of the
6 defendant -

- 7 a. cannot be located upon the exercise of due diligence;
8 b. has been transferred or sold to, or deposited with, a third party;
9 c. has been placed beyond the jurisdiction of the court;
10 d. has been substantially diminished in value; or
11 e. has been commingled with other property which cannot be divided
12 without difficulty;

13 it is the intent of the United States of America, pursuant to Title 21, United States
14 Code, Section 853(p), to seek forfeiture of any properties of the defendant for the in
15 personam criminal forfeiture money judgment including, but not limited to, at least
16 \$3,504,912.21.
17

18 All pursuant to Title 18, United States Code, Section 981(a)(1)(C) with Title
19 28, United States Code, Section 2461(c); Title 21, United States Code, Sections 841,
20 853(a)(1), 853(a)(2), and (p); and Title 21, United States Code, Section 881(a)(6) with
21 Title 28, United States Code, Section 2461(c).
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FORFEITURE ALLEGATION TWO

(False Statement Relating to a Health Benefit Program)

1. The allegations contained in Counts Eight through Twenty-Nine of this Criminal Indictment are hereby realleged and incorporated herein by reference for the purpose of alleging forfeiture pursuant to Title 18, United States Code, Section 981(a)(1)(C) with Title 28, United States Code, Section 2461(c) and Title 18, United States Code, Section 982(a)(7).

2. Upon conviction of any of the felony offenses charged in Counts Eight through Twenty-Nine of this Criminal Indictment,

STEVEN A. HOLPER,

Defendant herein, shall forfeit to the United States of America, any property, real or personal, which constitutes or is derived from proceeds traceable to violations of Title 18, United States Code, Section 1035(a)(2), a specified unlawful activity as defined in Title 18, United States Code, Sections 1956(c)(7)(F), involving a Federal health care offense as defined in Title 18, United States Code, Section 24, or a conspiracy to commit such offense:

Defendant herein, shall forfeit to the United States of America, property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of Title 18, United States Code, Section 1035(a)(2), involving a Federal health care offense as defined in Title 18, United States Code, Section 24:

An in personam criminal forfeiture money judgment including, but not limited to, at least \$3,504,912.21 (property).

1 3. If any property subject to forfeiture pursuant to Title 18, United States
2 Code, Section 981(a)(1)(C) with Title 28, United States Code, Section 2461(c) and
3 Title 18, United States Code, Section 982(a)(7), as a result of any act or omission of
4 the defendant-

- 5 a. cannot be located upon the exercise of due diligence;
6 b. has been transferred or sold to, or deposited with, a third party;
7 c. has been placed beyond the jurisdiction of the court;
8 d. has been substantially diminished in value; or
9 e. has been commingled with other property which cannot be divided
10 without difficulty;

11 it is the intent of the United States of America, pursuant to Title 21, United States
12 Code, Section 853(p), to seek forfeiture of any properties of the defendant for the in
13 personam criminal forfeiture money judgment including, but not limited to, at least
14 \$3,504,912.21.

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1 All pursuant to Title 18, United States Code, Section 981(a)(1)(C) with Title
2 28, United States Code, Section 2461(c); Title 18, United States Code, Section
3 982(a)(7); Title 18, United States Code, Section 1035(a)(2); and Title 21, United
4 States Code, Section 853(p).

5
6 **DATED:** this 7th day of February, 2018.

7 **A TRUE BILL:**

8 /S/
9 FOREPERSON OF THE GRAND JURY

10 DAYLE ELIESON
11 United States Attorney

12 
13 KILBY MACFADDEN
14 ROBERT A. KNIEF
15 Assistant United States Attorneys